

EXHIBIT F



January 9, 2024

Norton Rose Fulbright US LLP
60 South Sixth Street, Suite 3100
Minneapolis, Minnesota 55402
United States of America

The Honorable Joan N. Ericksen
United States District Court
300 South Fourth Street
Minneapolis, MN 55415

Ben Hulse
Partner
Direct line +1 612 321 2272
ben.hulse@nortonrosefulbright.com

(VIA ECF)

Tel +1 612 321 2800
Fax +1 612 321 2288
nortonrosefulbright.com

Re: *In re Bair Hugger*, MDL No. 15-2666 – Request to Submit Rule 702 Motion

Dear Judge Ericksen:

On December 1, 2023, the amended Federal Rule of Evidence 702 went into effect. Under the remedial changes in this rule, Plaintiffs' general causation expert witness opinions are no longer admissible. Based on the amended rule, and on developments in the science confirming that the Bair Hugger does not increase the risk of periprosthetic joint infections, 3M asks for leave to file a renewed motion to exclude Plaintiffs' general causation medical experts.

The Eighth Circuit reversed exclusion of Plaintiffs' general causation medical experts by relying on a pre-*Daubert* gloss on Rule 702, holding that an expert opinion cannot be excluded unless "so fundamentally unsupported" that it would be useless to the jury. *In re Bair Hugger*, 9 F.4th 768, 778 (8th Cir. 2021), *quoting* *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988). The Eighth Circuit repeated that standard five times in its decision. The amendments to Rule 702 changed the law and make clear that the court must determine as part of its gatekeeping function that an expert opinion is supported by sufficient facts or data.¹

The Advisory Committee had decisions like *Bair Hugger* in mind in proposing the amendments: "[M]any courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a)." The Eighth Circuit made such an "incorrect application" in holding that "[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Bair Hugger*, 9 F.4th at 778.²

The science in the intervening years also justifies revisiting general causation. The Eighth Circuit characterized the parties' scientific dispute as "currently the focus of extensive scientific research and debate." *Bair Hugger*, 9 F.4th at 789. Even if that were true in 2019, when the appellate record closed, it is not true today. No independent medical or regulatory organization – including the FDA

¹Plaintiffs acknowledged that the new Rule 702 would change the standards when they urged the Supreme Court to deny review of the Eighth Circuit, arguing that then-proposed amendments "might obviate 3M's and amici's concerns" that the Eighth Circuit had vitiated district courts' gatekeeping role.

² As the Committee says, "weight" is grounds for admissibility only "once the court has found it more likely than not that the admissibility requirement has been met. . . . [I]t does not permit the expert to make claims that are unsupported by the expert's basis and methodology."

The Honorable Joan N. Ericksen
Page 2
January 9, 2024

^
NORTON ROSE FULBRIGHT

and the International Consensus Meeting on Musculoskeletal Infection – has revisited its rejection of Plaintiffs’ theories. The single, deeply flawed epidemiological study Plaintiffs rely upon (McGovern) has never been replicated since publication in 2011. Likewise, no study has ever cultured bacteria from the Bair Hugger blanket. On the contrary, studies have continued to find that forced air warming does not increase bacteria at the surgical site. For example, a recent study³ found no difference in bacterial loads on the floor, operating table, or operative limb between surgeries with forced air warming and surgeries without it.

Research has continued to support that the primary source of infection is the patient’s own skin. In another recent study, researchers found that 40% of patients swabbed with a widely used disinfectant remained culture-positive after disinfection.⁴ More generally, the *New England Journal of Medicine* published a comprehensive review of risk factors for periprosthetic joint infection and identified 27 such factors – forced air warming not among them.⁵ Outside the courtroom, Plaintiffs’ theories remain overwhelmingly rejected by the medical community. Moreover, the three medical experts cited by the Eighth Circuit have disappeared from the scene. Dr. Samet disclosed a report in 2017 and provided only a brief affidavit on the Jeans study in response to 3M’s reconsideration motion. Plaintiffs have never called him to testify. Dr. Stonnington has not appeared since *Gareis*. Plaintiffs have not disclosed Dr. Jarvis in any state court case since *O’Haver*. None has published an article based on his made-for-litigation opinions.

Now is the right time to decide this issue. 3M considered raising the amendments via case-specific Rule 702 motions. But the Court’s suggestion of remand means that such motions will be filed in district courts outside the Eighth Circuit, and not until late in 2024. There is no guarantee that the six trial-candidate cases remaining here will make it to the dispositive motion stage. The track record of prior bellwethers in the MDL is that most will be dismissed during discovery. Resolution of this litigation is best served by addressing general causation in the MDL under the Rule 702 amendments and the current state of the science.

Even if the Court concludes that the amendments have not changed Eighth Circuit law, 3M requests the Court still grant permission to file its motion. Entry of an order denying the motion will allow 3M to request certification under 28 U.S.C. § 1292(b). The criteria for certification are readily satisfied. Not only would review materially advance the termination of this litigation, but district courts throughout the Eighth Circuit would benefit from clarification of the law.

Very truly yours,

/s/ Benjamin W. Hulse

/s/ Mary S. Young

Benjamin W. Hulse
Co-Lead Counsel for Defendants

Mary S. Young
Co-Lead Counsel for Defendants

³Gemayel A., et al. Are intra-operative forced air warming devices a possible source of contamination during hand surgery? *Cureus*. 2023 Sep 30;15(9):e46287, online at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10615902>.

⁴Guarch-Perez et al. Bacterial reservoir in deeper skin is a potential source for surgical site and biomaterial-associated infections. *J Hosp Infect*. 2023 Oct;140:62-7, online at [https://www.journalofhospitalinfection.com/article/S0195-6701\(23\)00243-8/fulltext](https://www.journalofhospitalinfection.com/article/S0195-6701(23)00243-8/fulltext).

⁵Patel R. Periprosthetic joint infection. *N. Engl. J. Med*. 388:251-62, online at <https://www.nejm.org/doi/pdf/10.1056/NEJMra2203477>.